

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

<p>IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION</p>	
<p>THIS DOCUMENT RELATES TO:</p> <p><i>The City of New York v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 04-CV-06054</p> <p><i>County of Albany v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0425</p> <p><i>County of Allegany v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0236</p> <p><i>County of Broome v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0456</p> <p><i>County of Cattaraugus v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0256</p> <p><i>County of Cayuga v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0423</p> <p><i>County of Chautauqua v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0214</p> <p><i>County of Chemung v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-6744</p> <p><i>County of Chenango v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0354</p> <p><i>County of Columbia v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0867</p> <p><i>County of Cortland v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0881</p> <p><i>County of Dutchess v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 05-CV-6458</p> <p><i>County of Essex v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0878</p> <p><i>County of Fulton v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0519</p>	<p>MDL NO. 1456 Civil Action No. 01-12257-PBS</p> <p>Judge Patti B. Saris</p> <p><b>PLAINTIFFS' OPPOSITION TO ELI LILLY AND COMPANY'S SEPARATE MEMORANDUM IN SUPPORT OF MOTION TO DISMISS</b></p>

*County of Genesee v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-00267

*County of Greene v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0474

*County of Herkimer v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-00415

*County of Jefferson v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0715

*County of Lewis v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0839

*County of Madison v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-00714

*County of Monroe v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-6148

*County of Nassau v. Abbott Laboratories, Inc., et al.*  
E.D.N.Y. Case No. 04-CV-05126

*County of Niagara v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-06296

*County of Oneida v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0489

*County of Onondaga v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0088

*County of Ontario v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-6373

*County of Orleans v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-6371

*County of Putnam v. Abbott Laboratories, Inc., et al.*  
S.D.N.Y. Case No. 05-CV-04740

*County of Rensselaer v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-00422

*County of Rockland v. Abbott Laboratories, Inc., et al.*  
S.D.N.Y. Case No. 03-CV-7055

*County of Schuyler v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-6387

*County of Seneca v. Abbott Laboratories, Inc., et al.*

W.D.N.Y. Case No. 05-CV-6370

*County of St. Lawrence v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0479

*County of Saratoga v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0478

*County of Steuben v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-6223

*County of Suffolk v. Abbott Laboratories, Inc., et al.*  
E.D.N.Y. Case No. 03-CV-12257

*County of Tompkins v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0397

*County of Ulster v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 06-CV-0123

*County of Warren v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0468

*County of Washington v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0408

*County of Wayne v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-06138

*County of Westchester v. Abbott Laboratories, Inc., et al.*  
S.D.N.Y. Case No. 03-CV-6178

*County of Wyoming v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-6379

*County of Yates v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-06172

## INTRODUCTION

Eli Lilly and Company's ("Lilly") individual memorandum (hereinafter "Lilly MTD") seeks the dismissal of all of plaintiffs' claims on the grounds that the Court dismissed similar claims against Lilly as part of the "Suffolk 13" in the matter styled *County of Suffolk v. Abbott Labs., et al.* (Civ. Action No. 1:03-cv-10643) (MDL 1456) ("*Suffolk*"). Lilly contends that the dismissal in Suffolk requires the dismissal of plaintiffs' claims in the instant action.

Plaintiffs have made sufficient allegations to sustain their claims. Plaintiffs allege fraudulent AWP's for every Lilly drug for which they seek relief and properly use Lilly's own market prices to demonstrate Lilly's artificially inflated spreads.<sup>1</sup> Plaintiffs also sufficiently allege facts in detail to support their Best Price/Rebate claims, including that the government is investigating Lilly's pricing practices. This Court has already ruled that such allegations are directly relevant to plaintiffs' claims. The specificity of these allegations satisfies the particularity requirements of Fed. R. Civ. P. 9(b) as well as the Court's prior rulings, including those in *Suffolk*.<sup>2</sup> Finally, and contrary to Lilly's assertion, the Court did not dismiss any non-fraud based state claims against Lilly in *Suffolk*. For the reasons set forth below, Lilly's motion to dismiss should be denied in its entirety.<sup>3</sup>

## DISCUSSION

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<sup>1</sup> See Corrected Consolidated Complaint, filed on June 22, 2005 ("Consolidated Complaint" or "CC") at ¶¶ 434-448, Exh. A; Nassau Second Amended Complaint, filed on January 6, 2006 ("Nassau SAC" or "NSAC") at ¶¶ 372-374, Exh. B.

<sup>2</sup> See *In re Pharm. Indus. Average Wholesale Price Litig.*, 339 F.Supp.2d 165, 173 ("*Suffolk I*"); *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-12257, 2004 WL 2387125, at \*3 (D. Mass. Oct. 26, 2004) ("*Suffolk II*"); *In re Pharm. Indus. Average Wholesale Price Litig.*, Memorandum and Order at 1-2 (D. Mass. April 8, 2005) ("*Suffolk III*").

<sup>3</sup> All other causes are addressed in Plaintiffs' Consolidated Opposition to Defendants Joint Motion to Dismiss, filed April 17, 2006 (referred to herein as "Con. Opp."). Insofar as Lilly incorporates Merck & Co.'s individual brief here, plaintiffs address those arguments in their opposition to Merck's individual motion to dismiss, which opposition is incorporated herein. That brief also was filed April 17, 2006.

Lilly does not challenge any of the allegations of the complaints as insufficient. *See* Lilly MTD at 1. Lilly's principal arguments are that plaintiffs do not list spreads relating to Lilly in their exhibits and that Lilly is not named in any other lawsuit concerning AWP. *See id.* Otherwise, Lilly's basis for its motion is that plaintiffs' allegations are identical to that of Suffolk and as such plaintiffs' complaints should be dismissed. *Id.* Lilly's arguments are misplaced. *See* Exhibit A to Con. Opp. detailing differences between Suffolk and the Consolidated Complaint.

**A. Plaintiffs' Fraud-Based AWP Claims Are Pled With Sufficient Particularity**

In order to maintain fraud-based AWP Claims this Court has previously ruled that plaintiffs must set forth factual allegations regarding spread, internal documents or government investigations from which an inference of fraud can reasonably be made. *See Suffolk II*, 2004 WL 2387125 at \*2; *In re Pharm. Indus. Average Wholesale Price Litig.*, 307 F. Supp. 2d 196 at 209 (D. Mass. 2004) ("*Pharm. III*") (recognizing an industry-wide practice of inflating AWP's and not requiring a specific spread for every drug of each manufacturer). The Court specifically held that the use of a calculated average sales price for a drug was insufficient. *See Suffolk III* at 2.

Plaintiffs have complied with the Court's prior rulings by alleging (1) fraudulent AWP's for all Lilly products for which plaintiffs paid; (2) exorbitant spreads calculated based on Lilly's own available actual market prices<sup>4</sup> -- as opposed to average prices -- for Lilly products; (3) substantial spreads between an actual market price and the fraudulent AWP's for Lilly drugs paid for by plaintiffs that range up to 612%; (4) that Lilly negotiates the purchase price of its drugs at deep discounts with group purchasing organizations ("GPOs"), providers and PBMs; (5) that Lilly utilized an "Equal Access Upfront Discount Programs" for all doses of Zyprexa and Symbyax that offered certain GPO

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<sup>4</sup>Allegations of spreads are not limited to Exhibit B. Plaintiffs allege spreads based on actual market prices for (continued...)

members an upfront discount of 8% off the related WACs in exchange for favorable placement on the GPO's formulary; (6) that Lilly admitted in its SEC Form 10K for fiscal year end 2002 that it received a subpoena from the U.S. Department of Justice pursuant to an investigation into Lilly's communications with physicians for promotion of its drug Evista for indications not approved by the FDA; (7) that in its SEC Form 10K for the fiscal year 2004, Lilly stated that the investigation by the DOJ might expand to Zyprexa; (8) that the U.S. Attorney's Office in Pennsylvania is investigating its marketing practices for off-label marketing practices relating to Zyprexa, Prozac and Prozac weekly;<sup>5</sup> and (9) the existence of government investigations concerning Medicaid and improper pricing practices and failures to comply with Best Price rebate requirements by Lilly being conducted by both Senate Finance Committee and the House Subcommittee of Oversight and Investigation of the Committee of Energy and Commerce.<sup>6</sup> See CC ¶¶434-448, Exh. A; NSAC ¶¶372-374, Exh. B

Individually and collectively, these allegations are more than sufficient to draw a reasonable and sound inference that Lilly fraudulently established AWP's. See *U.S. ex rel. Franklin v. Parke Davis*, 147 F.Supp.2d 39, 49 (D. Mass 2001) (Saris, J.) ("[W]here the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible.").

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Lilly in the text of the complaints. See CC ¶¶439-40, 443, Exh. A; NSAC ¶¶372-374, Exh. B.

<sup>5</sup>Investigations into Lilly's off-label marketing of Evista, Zyprexa, Prozac and Prozac Weekly are relevant to plaintiffs' claims because Lilly is being investigated for skirting laws meant to regulate pharmaceuticals, similar to skirting the laws and regulations concerning Best Price and Medicaid pricing. Both this case and those investigations concern drugs and Lilly's disregard of its statutory and regulatory obligations. The investigations clearly suggest fraudulent behavior with financial motive, thus it is arguably relevant to plaintiffs' Best Price and AWP claims.

<sup>6</sup>The Court has specifically held that in order to maintain AWP-related claims, plaintiffs must "set forth [] factual allegations regarding a spread, internal documents or government investigations from which an inference of fraud [could] reasonably be made..." (emphasis added). See *Suffolk II*, 2004 WL 2387125 at \*2; *Pharm III*, 307 F. Supp. 2d at 209 (D. Mass. 2004) ("*Pharm. III*"). The Court does not require an adjudication of the lawsuits or government investigations.

Accordingly, Lilly's motion to dismiss should be denied.

**B. Plaintiffs' Fraud-Based Best Price/Rebate Claims Are Pled With Sufficient Particularity**

In order to maintain Best Price/Rebate claims, plaintiffs must "set forth minimal facts with respect to (1) the allegedly fraudulent or false price reported to the state for any specific drug; or (2) any information showing a company-wide scheme to misstate Best Prices." *Suffolk II*, 2004 WL, 2387125 at \*3.

Plaintiffs have done both. First, plaintiffs allege the name of every Lilly drug for which they assert Best Price claims. *See* CC ¶¶ 434-448, Exh. A; NSAC ¶¶ 372-374, Exh. B. Second, plaintiffs allege a company-wide scheme and strategy whereby Lilly's sales force had the discretion to utilize aggressive discounts and off-invoice pricing to lower prices and maximize sales. Plaintiffs allege off-invoice pricing allows a manufacturer to lower the net cost to the purchaser while concealing the actual cost beneath the fiction of a higher invoice. *See* CC ¶ 153; NSAC ¶ 122.

In addition, plaintiffs allege that: (1) Lilly utilized aggressive up-front discounts to gain access to GPO formularies and to compete with other therapeutically equivalent drugs; (2) Lilly utilized off-invoice pricing, including rebates, discounts and free products; (3) Lilly is keenly aware that its purchaser's profits depend on the reimbursement rates of Lilly drugs and can achieve greater sales through price adjustments and discounts, while not lowering AWP's, (4) Lilly utilized, and did not account for, off-invoice price reductions, rebates and discounts which resulted in falsely inflated invoices, the effect of which was to mask the true cost of the drugs on the invoice and maintain a higher fictional invoice price; (5) both the Senate Finance Committee and the House Subcommittee of Oversight and Investigation of the Committee of Energy and Commerce are investigating Lilly for improper pricing practices and failures to comply with Best Price rebate requirements. These



allegations show a company-wide scheme implicating all Lilly products. *See* CC ¶¶153, 387-400, Exh. A; NSAC ¶¶372-374, Exh. B. Individually and collectively, these claims satisfy Fed. R. Civ. P. 9(b). Thus, Lilly's motion to dismiss should be denied.

**C. There is No Basis to Dismiss Plaintiffs' Claims Because of Suffolk**

Lilly requests dismissal of all plaintiffs' claims on the grounds that the allegations have been ruled on and dismissed in *Suffolk*. *See* Lilly MTD at 1.

This is incorrect. *See* Con. Opp. at Procedural History. The Court's *Suffolk III* decision -- regarding whether Suffolk satisfied 9(b) with respect to the "Suffolk 13 +6" -- in no way modified either its *Suffolk I* or *Suffolk II* decisions. There, the Court sustained Suffolk's AWP-based and Best Price-based unjust enrichment claims and claims for violation of 18 N.Y.C.R.R. §515.2(b)(4) & (5) against the Suffolk 13 +6. In *Suffolk II*, the Court expressly held that Rule 9(b) did not apply to these claims, as they "do not require a pleading of fraud or mistake." *Suffolk II*, 2004 WL, 2387125 at \*2. Thus, at the very least, these claims survived in *Suffolk*. Lilly does not dispute any of plaintiffs' non-fraud based claims.

Moreover, plaintiffs' allegations are decidedly different from that in *Suffolk*. *See* Con. Opp., Exhibit A. Given that the pending motion to dismiss is the test on the sufficiency of plaintiffs' allegations, in the event that the Court deems plaintiffs' allegations in support of its claims insufficient, plaintiffs hereby request leave to amend in order to provide even more specific detail concerning Lilly's pricing misconduct and harm to New York Medicaid. *See Whelan v. Intergraph Corp.*, 889 F.Supp. 15, 19 at fn 4. (D. Mass 1995) (citing *Hayduk v. Lanna*, 775 F.2d 441 at 445 (1985) ("federal courts must be liberal in allowing parties to amend their complaints.")).



## **CONCLUSION**

For the reasons set forth herein, Lilly's individual motion to dismiss should be denied in its entirety.

Dated: April 24, 2006.

Respectfully submitted,

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except Nassau, by**

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